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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,277	05/14/2001	Nathan Lewis	18564001921	2894

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EXAMINER	
HANDY, DWAYNE K	
ART UNIT	**PAPER NUMBER**
1743	12

DATE MAILED: 07/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

A9-12

Office Action Summary

Application No.	Applicant(s)
09/855,277	Lewis et al.
Examiner	**Art Unit**
Dwayne K. Handy	1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 7, 2003*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *24 and 26-33* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *24 and 26-31* is/are rejected.

7) ☒ Claim(s) *32 and 33* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

1.The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 32 and 33 were previously rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In light of applicant's arguments submitted 5/7/03, this rejection has been removed.

Inventorship

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 24, 26, 27, 29, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekstrom (5,971,937) in view of Raymond et al. (6,282,441). Ekstrom teaches a method and apparatus for measuring a blood alcohol concentration as well as for securing the reliability of the measured value. The apparatus is comprised of sensor elements (1) for obtaining both a measured alcohol concentration and a carbon dioxide concentration, as well as output elements

for providing a result based on the measurements (Abstract). The apparatus is described in general in column 10, lines 14-45. The apparatus contains multiple optical infrared sensors which measure alcohol concentration. The Examiner would consider the cited passage from column 10 as teaching the limitations of an analyte that is a marker gas (an alcohol marking the condition of drunkenness) measured by an opto-electrical device. These limitations are in the dependent claims cited as rejected: claims 26, 27, and 29. As to the independent method claims, the Examiner directs applicant to column 9 where the reference teaches the use of multiple sampling of breath samples and comparing the results to improve the reliability of the alcohol concentration measurements. This is also shown in the claims. Ekstrom recites the use of multiple measurements and then comparing them to insure an accurate and reliable measurement of the analyte based on the readings obtained over time. That is, the sensor array is contacted with a first sample to identify the analyte. Then the sensor array is contacted with exhaled breath a second time and the two sample readings are compared. The Examiner believes this meets the basic limitations of the independent claims 24 and 31. Since the sensors record both alcohol and carbon dioxide, the Examiner would consider these results to constitute a "profile" as cited in claim 31. Again, the method or concept of taking multiple samples at various times to insure the reliability of the sample is cited throughout the reference, but the Examiner believes that the claims and column 9, lines 23-67 to be particularly relevant to the instant claims. Ekstrom does not teach storing the profile date or analysis results in a computer readable storage format. Raymond et al. (6,282,441) teaches a health monitoring system. The system may be used as a

diagnostic tool in monitoring the health of patients. The preferred embodiment of the device includes a data management system linked with a plurality of physiological data collection devices. The system is described in further detail in columns 5 and 6 and includes monitors (108) which monitor the patient and feed data to a dat logger. This logger later stores the accumulated information in a database which may be accessed at any time to determine the status of the patient based on a comparison between the information stored in the database and current or baseline information about the patient. It would have been obvious to one of ordinary skill in the art to combine the database teachings of Raymond with the method of Ekstrom. One would add the database storage to allow for comparisons between the two profiles at a later date or numerous times as taught in Raymond.

7. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ekstrom and Raymond, and further in view of Lemelson (5,787,885). Ekstrom and Raymond as cited above, teach every element of claim 30 except for a neural net trained against known analytes. Lemelson teaches a body fluid analysis system. The system may be used to analyze breath samples (col. 3, lines 25-45) and contains sensor elements whose output is analyzed by neural network computer algorithms (col. 9, lines 5-35). It would have been obvious to one of ordinary skill in the art to combine the neural net of Lemelson with the combined teachings of Ekstrom and Raymond. One would add the neural net algorithms to perform diagnostic algorithms as suggested by Lemelson (col. 9, line 11).

8. Claims 24, 28 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rounbehler et al. in view of Ekstrom and further in view of Raymond et al. (6,282,441). Rounbehler teaches disease diagnosis by vapor sample analysis. The basic method is recited in claims 1-3 and includes obtaining a vapor sample, analyzing the sample by luminescence analysis and reporting the presence or absence of disease based on analysis of the vapor. In describing embodiments of the device, Rounbehler et al. teaches that "The analysis may be arranged to diagnose infections, precancerous conditions or disease generally in which tissue decay is present. For example, damage to the intestine may be detected. The breath analyzer in certain embodiments can be used to detect infections, or it can also be used to detect and determine the origin of bad breath in a patient. Other diseases that can be detected include ulcers, viral infections, bacterial infections, liver diseases (e.g. hepatitis and cirrhosis), internal body infections, and heart disease...." Rounbehler does not teach multiple sample readings which are compared to each other. Ekstrom teaches a method and apparatus for measuring a blood alcohol concentration as well as for securing the reliability of the measured value. Ekstrom recites the use of multiple measurements and then comparing them to insure an accurate and reliable measurement of the analyte based on the readings obtained over time. That is, the sensor array is contacted with a first sample to identify the analyte. Then the sensor array is contacted with exhaled breath a second time and the two sample readings are compared. The reason for taking multiple samples at various times and comparing them is to insure the

reliability of the sample. This is taught by the reference in column 9, lines 23-67. It would have been obvious to one of ordinary skill in the art to combine the multiple reading and comparing steps of Ekstrom with the method of Rounbehler. Adding the multiple reading and comparison steps of Ekstrom would help to insure the reliability of the sample reading(s). This would be advantageous when using the sample readings for diagnosing illness or disease since the user would want to make an accurate diagnosis. As to the dependent claim limitations, it would have been obvious to one of ordinary skill in the art that a diagnosed condition which may be an internal body infection from a bacteria would include pneumonia or sinus infections since these are caused by bacterial infection. The Examiner believes this would meet the limitations of dependent claims 28, 32, and 33. The combined teachings of Rounbehler et al. and Ekstrom et al. do not teach storing teach storing the profile date or analysis results in a computer readable storage format. Raymond et al. (6,282,441) teaches a health monitoring system. The system may be used as a diagnostic tool in monitoring the health of patients. The preferred embodiment of the device includes a data management system linked with a plurality of physiological data collection devices. The system is described in further detail in columns 5 and 6 and includes monitors (108) which monitor the patient and feed data to a data logger. This logger later stores the accumulated information in a database which may be accessed at any time to determine the status of the patient based on a comparison between the information stored in the database and current or baseline information about the patient. It would have been obvious to one of ordinary skill in the art to combine the data base teachings of Raymond with the method of Ekstrom. One

would add the database storage to allow for comparisons between the two profiles at a later date as taught in Raymond.

Response to Arguments

9. In light of the amendments and arguments submitted 7/8/02, the previous rejections made by the Examiner in the previous Office Action (Paper No. 9) involving the 102 rejections under Ekstrom have been removed. The Examiner believes, however, that the addition of a new reference - Raymond - contains the features which were lacking in the original rejection under Ekstrom. The Examiner would, however, like to address applicant's arguments directed against the reference Ekstrom and the limitation of "contacting" the sensor array. The Examiner disagrees with applicant's assertion that the array of Ekstrom does not contact the breath to be analyzed. While it is true that the breath sample must travel through a pathway to reach the IR sensors of Ekstrom, the Examiner fails to see how this is not considered to be contacting the sensor array. The radiation from the sensor contacts the air stream in the channel. Applicant has even conceded this in the last sentence of these arguments in stating that the infrared radiation comes in contact with the air stream in the channel! The Examiner considers this "contact" to meet the limitation of the claim as written since applicant has merely used the term "contact" in the claim with no other qualifying terms (i.e. no actual physical contact is specified). This contacting of radiant energy - which the Examiner considers to be part of the sensor - to a sample is how many opto-electronic sensors work: the radiation from the sensor contacts the analyte,

undergoes some change, and the resulting change is read and used to quantify the analyte present.

As for the limitation of comparing the two profiles, the Examiner believes applicant is arguing beyond the scope of the claims. In arguments, applicant has pointed out that Ekstrom compares carbon dioxide and oxygen values with predetermined values. This is not, however, the "profiles" the Examiner referred to in the original rejection. In the rejection , the Examiner referred to the multiple readings that were used to insure an accurate and reliable measurement of the analyte based on readings over time (column 9 and claims). This does involve a comparison between two readings - which the Examiner considers to be "profiles".

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K. Handy whose telephone number is (703)-305-0211.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to whose telephone number is . The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703)-308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703)-772-9310..

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0661.

Jill Warden
Supervisory Patent Examiner
Technology Center 1700

dkh

July 14, 2003